

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re reissue application of	)	
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FERNANDO J. ISAZA, ET AL.	)	Docket No. PURIT 54796
	)	
Serial No.	)	March 16, 2001
	)	
Filed:	)	Los Angeles, California 90045
	)	
U. S. Patent No. 5,881,717	)	
	)	
Issued: March 16, 1999	)	
	)	
For: SYSTEM AND METHOD FOR	)	Express Mail No.:
ADJUSTABLE DISCONNECTION	)	EL590184683US
SENSITIVITY FOR	)	
DISCONNECTION AND	)	
OCCLUSION DETECTION IN A	)	
PATIENT VENTILATOR	)	

PRELIMINARY AMENDMENT

BOX REISSUE  
Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This Preliminary Amendment is being filed concurrently with a Reissue application filed under 37 CFR 1.173, based upon U. S. Patent No. 5,881,717, issued: March 16, 1999.

198422.1

Please enter the following amendments prior to examination of the application.

IN THE ABSTRACT:

Please amend the abstract as follows:

The system and method for detecting disconnection [and occlusion] of a tubing system of a patient ventilator detects disconnection of the tubing system, opens the exhalation valve, delivers an idle flow of breathing gas to the tubing system, disables breath triggering, and generates an alarm. A reconnection of the tubing system can also be detected, to initiate resumption of pressure supported inspiration. [For occlusion detection, the pressure drop in the tubing system is determined by pressure sensors in the inspiratory and expiratory airways of the tubing system. The two pressure drop values are compared, and once occlusion is detected, an alarm is generated, and the ventilator responds to protect the patient from over distension. Abatement of the occlusion can also be monitored in a pressure based occlusion status cycling mode, and the ventilator can revert back to normal ventilation when either circuit occlusion or exhaust port occlusion are not detected.]

IN THE SPECIFICATION:

In column 2, at lines 18-45, please amend the paragraph as indicated below:

In one currently preferred embodiment, the invention accordingly provides for a method for detecting disconnection [or occlusion] of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide [for providing] breathing gas to a patient [during the exhalation phase of a breath cycle, the exhalation phase having a plurality of control intervals, with each of the control intervals having a predetermined duration]. A method of the invention comprises the steps of [delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle,] determining an onset of an exhalation phase of the breath cycle, [suspending gas flow delivery to the patient tubing system during the exhalation phase of the breath cycle,] and monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of the exhalation phase of the breath cycle to determine whether a condition indicating disconnection of the patient tubing system has occurred. The exhalation pressure in the patient tubing system is monitored during a plurality of control intervals of the exhalation phase of the breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred; and a disconnection signal indicating disconnection of the patient tubing system is generated responsive to the exhalation flow and the pressure in the patient tubing system if the condition indicating occlusion of the patient

tubing system has not occurred, and if the condition indicating disconnection of the patient tubing system has occurred.

From column 2, line 46, to column 3, line 6, please amend the paragraph as indicated below:

In another currently preferred embodiment, the invention provides for a system for detecting disconnection [or occlusion] of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide [for providing] breathing gas to a patient [during the exhalation phase of a breath cycle, the exhalation phase having a plurality of control intervals, with each of the control intervals having a predetermined duration]. The system comprises [means for delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle,] means for determining an onset of an exhalation phase of the breath cycle, [means for suspending gas flow delivery to the patient tubing system during the exhalation phase of the breath cycle,] and means for monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of the exhalation phase of the breath cycle to determine whether a condition indicating disconnection of the patient tubing system has occurred. The system may include means for monitoring exhalation pressure in the patient tubing system during a plurality of control intervals of the exhalation phase of the breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred, and means for generating a

disconnection signal indicating disconnection of the patient tubing system responsive to the exhalation flow and the pressure in the patient tubing system if the condition indicating occlusion of the patient tubing system has not occurred, and if the condition indicating disconnection of the patient tubing system has occurred.

In column 3, at lines 16-35, please amend the paragraph as indicated below:

The invention also provides for a method for detecting occlusion of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide [for providing] breathing gas to a patient [during the exhalation phase of a breath cycle, the exhalation phase having a plurality of control intervals, each of the control intervals having a predetermined duration]. A method of the invention comprises the steps of delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle, determining an onset of an exhalation phase of the breath cycle, [suspending gas flow delivery to the patient tubing system during the exhalation phase of the breath cycle,] monitoring delivered flows and exhaled flows; monitoring exhalation pressure in the patient tubing system during a plurality of control intervals of the exhalation phase of the breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred; and generating a occlusion, signal indicating occlusion of the patient tubing system responsive to the pressure in the patient tubing system if the condition indicating occlusion of the patient tubing system has occurred.

In column 3, at lines 36-56, please amend the paragraph as indicated below:

In another presently preferred embodiment, the invention provides for a system for detecting occlusion of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide [for providing] breathing gas to a patient [during the exhalation phase of a breath cycle, the exhalation phase having a plurality of control intervals, with each of the control intervals having a predetermined duration]. The system comprises means for delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle, means for determining an onset of an exhalation phase of the breath cycle, [means for suspending gas flow delivery to the patient tubing system during the exhalation phase of the breath cycle,] means for monitoring delivered flows and exhaled flows, means for monitoring exhalation pressure in the patient tubing system during a plurality of control intervals of the exhalation phase of the breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred, and means for generating an occlusion signal indicating occlusion of the patient tubing system responsive to the pressure in the patient tubing system if the condition. indicating occlusion of the patient tubing system has occurred.

From column 3, line 57, to column 4, line 3, please amend the paragraph as indicated below:

[In a presently preferred embodiment, the invention also provides for

generation of an occlusion signal indicating occlusion of the patient tubing system if the condition indicating occlusion of the patient tubing system has occurred.] In a currently preferred embodiment, an occlusion alarm signal is generated, the exhalation valve is opened, an idle flow is delivered, and flow and pressure are monitored in an occlusion status cycling mode to determine whether a condition indicating abatement of occlusion of the patient tubing system has occurred. The invention also provides for initiation of the resumption of flow of breathing gas to the patient tubing system during an inspiratory phase of a breath cycle if a condition indicating abatement of occlusion of the patient tubing system has occurred.

From column 4, line 66, to column 5, line 25, please amend the paragraph as indicated below:

In a first set of criteria, a condition indicating disconnection of the patient tubing system has occurred can be declared if, during a control interval, the pressure in the tubing system as sensed by a pressure sensor in the exhalation line of the tubing system falls [outside] within a [desired,] predetermined range, and exhalation flow is less than a desired, predetermined threshold, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase. In a preferred embodiment of the first set of criteria, the control interval is 5 msec., and all of the following three conditions must be met at some time during the first 200 msec. of an exhalation phase,

for a contiguous period of 100 consecutive milliseconds:

If  $\text{Pat\_press}(n) \geq -0.5 \text{ cmH}_2\text{O}$

AND  $\text{Pat\_Press}(n) \leq 0.5 \text{ cmH}_2\text{O}$

AND  $\text{Dry\_exh\_flow}(n) \leq 0.5 \text{ lpm}$

where  $\text{Pat\_press}(n)$  is the pressure in the tubing system as sensed by a pressure sensor in the exhalation line of the tubing system during a control interval, and  $\text{Dry\_exh\_flow}(n)$  is the exhalation flow as measured by the exhalation flow sensor, compensated for the breathing gas mix and for humidity in the gas to represent dry conditions. Typically, an estimated amount of water vapor flow is removed from the initial flow measurement from the exhalation flow sensor  $\text{Exh\_flow}$ . Then, the remaining dry flow is compensated for the expected gas mix ( $\text{N}_2$ ,  $\text{O}_2$ ).

In column 9, at lines 42-48, please amend the paragraph as indicated below:

For occlusion detection purposes Eq. 5 is modified to account for the pressure and flow [low] sensor accuracies (i.e. offset & gain drift). The determination of  $dP$  is thus typically adjusted for such factors as offset and gain drift, based upon the following equation:

$$dP_{\text{meas}} = (P_{\text{insp}} - P_{\text{exh}}) - (0.7 + \text{Abs}(P_{\text{insp}}) * 0.062)$$

(Eq. 6)



IN THE CLAIMS:

Please cancel Claims 6-8, 10-16, 22-24, and 26-55.

Please amend the claims as is indicated below:

1. (Amended) A method for detecting disconnection [and occlusion] of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide [for providing] breathing gas to a patient [during the exhalation phase of a breath cycle], [said] an exhalation phase of a breath cycle having a plurality of control intervals, comprising the steps of:

[delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle;]

determining an onset of an exhalation phase of said breath cycle;

[suspending gas flow delivery to the patient tubing system during said exhalation phase of said breath cycle;]

monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle to determine

whether a condition indicating disconnection of the patient tubing system has occurred;

[monitoring exhalation pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred;] and generating a disconnection signal indicating disconnection of the patient tubing system responsive to said exhalation flow and said pressure in said patient tubing system [if said condition indicating occlusion of the patient tubing system has not occurred, and] if said condition indicating disconnection of the patient tubing system has occurred.

2. (Amended) The method of Claim 1, wherein said tubing system includes an exhalation line, and said step of monitoring exhalation flow and pressure in the patient tubing system comprises sensing pressure and flow in said exhalation line, and declaring disconnection of the patient tubing system has occurred if, during a control interval, the pressure in the exhalation line is [less than or greater than] within a predetermined pressure range, and if exhalation flow is less than a predetermined flow threshold, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase.

3. (Amended) [The method of Claim 1,] A method for detecting

disconnection of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide breathing gas to a patient, an exhalation phase of a breath cycle having a plurality of control intervals, comprising the steps of:

determining an onset of an exhalation phase of said breath cycle;

monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle to determine whether a condition indicating disconnection of the patient tubing system has occurred;

monitoring exhalation pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred; and

generating a disconnection signal indicating disconnection of the patient tubing system responsive to said exhalation flow and said pressure in said patient tubing system if said condition indicating occlusion of the patient tubing system has not occurred, and if said condition indicating disconnection of the patient tubing system has occurred;

wherein said tubing system includes an exhalation line, and said step of monitoring exhalation flow and pressure in the patient tubing system comprises sensing pressure and flow in said exhalation line, and declaring disconnection of the patient tubing system has occurred if, during a control interval, the pressure in the exhalation line is [less than or greater than] within a predetermined pressure range, and if exhalation flow

is less than a disconnection flow limit threshold based upon a flow target and a predetermined disconnection sensitivity, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase.

4. (Amended) [The method of Claim 1, wherein said tubing system includes an exhalation line, and said step of monitoring exhalation flow and pressure in the patient tubing system comprises sensing flow in said exhalation line,] A method for detecting disconnection of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide breathing gas to a patient, comprising the steps of:

delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle;

monitoring a desired flow target of breathing gas; and

declaring disconnection of the patient tubing system has occurred if [a] the desired flow target is greater than or equal to a maximum flow threshold, and the duration of a current inspiration is greater than or equal to a maximum allowed spontaneous inspiration time.

5. (Amended) [The method of Claim 1,] A method for detecting

disconnection of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide breathing gas to a patient, an exhalation phase of a breath cycle having a plurality of control intervals, comprising the steps of:  
determining an onset of an exhalation phase of said breath cycle;  
monitoring exhalation flow in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle; and

wherein said tubing system includes an exhalation line, and said step of monitoring exhalation flow and pressure in the patient tubing system comprises sensing flow in said exhalation line from the beginning of an inspiration to the beginning of an exhalation, determining an exhalation volume from the sensed flow from the beginning of the inspiration to the beginning of the exhalation, and declaring disconnection of the patient tubing system has occurred if the exhalation volume is less than the integral of the net flow from the beginning of inspiration to the beginning of exhalation with respect to time, multiplied by a proportional factor and a disconnection sensitivity factor, for three consecutive breaths.

17. (Amended) A system for detecting disconnection [and occlusion] of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide [for providing] breathing gas to a patient [during the exhalation phase of a breath cycle, said exhalation phase having a plurality of control intervals], the

system comprising:

[means for delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle;]

means for determining an onset of an exhalation phase of said breath cycle;

[means for suspending gas flow delivery to the patient tubing system during said exhalation phase of said breath cycle;]

means for monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle to determine whether a condition indicating disconnection of the patient tubing system has occurred;

[means for monitoring exhalation pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle to determine whether a condition indicating occlusion of the patient tubing system has occurred;] and

means for generating a disconnection signal indicating disconnection of the patient tubing system responsive to said exhalation flow and said pressure in said patient tubing system [if said condition indicating occlusion of the patient tubing system has not occurred, and] if said condition indicating disconnection of the patient tubing system has occurred.

18. (Amended) The system of Claim 17, wherein said tubing system includes an exhalation line, and said means for monitoring exhalation flow and pressure in the patient tubing system comprises a pressure sensor connected to said exhalation line and a flow sensor connected to said exhalation line, and means for declaring disconnection of the patient tubing system has occurred if, during a control interval, the pressure in the exhalation line is within [less than or greater than] a predetermined pressure range, and if exhalation flow is less than a predetermined flow threshold, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase.

19. (Amended) [The system of Claim 17,] A system for detecting disconnection of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide breathing gas to a patient, an exhalation phase of a breath cycle having a plurality of control intervals, comprising:  
means for determining an onset of an exhalation phase of said breath cycle;  
means for monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle;  
and

wherein said tubing system includes an exhalation line, and said means for monitoring exhalation flow and pressure in the patient tubing system comprises a pressure sensor connected to said exhalation line and a flow sensor connected to said exhalation line, and means for declaring disconnection of the patient tubing system has occurred if, during a control interval, the pressure in the exhalation line is within [less than or greater than] a predetermined pressure range, and if exhalation flow is less than a disconnection flow limit threshold based upon a flow target and a predetermined disconnection sensitivity, for a contiguous period of consecutive control intervals within a predetermined initial period of time following onset of an exhalation phase.

20. (Amended) [The system of Claim 17, wherein said tubing system includes an exhalation line, and said means for monitoring exhalation flow and pressure



in the patient tubing system comprises a flow sensor connected to said exhalation line,] A system for detecting disconnection of a patient tubing system of a pneumatically controlled ventilator system used to provide a desired flow target of breathing gas to a patient, comprising:

means for delivering a flow of breathing gas to a patient during an inspiratory phase of a breath cycle; and

means for declaring disconnection of the patient tubing system has occurred if a desired flow target is greater than or equal to a maximum flow threshold, and the duration of a current inspiration is greater than or equal to a maximum allowed spontaneous inspiration time.

21. (Amended) [The system of Claim 17,] A system for detecting disconnection of a patient tubing system of a pneumatically driven, electronically controlled ventilator system used to provide breathing gas to a patient, an exhalation phase of a breath cycle having a plurality of control intervals, comprising:

means for determining an onset of an exhalation phase of said breath cycle;

means for monitoring exhalation flow and pressure in the patient tubing system during a plurality of control intervals of said exhalation phase of said breath cycle;  
and

wherein said tubing system includes an exhalation line, and said means for

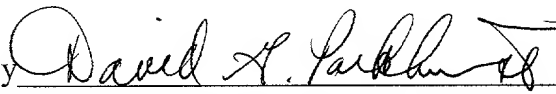
monitoring exhalation flow and pressure in the patient tubing system comprises a flow sensor connected to said exhalation line for measuring exhalation flow from the beginning of an inspiration to the beginning of an exhalation, means for determining an exhalation volume from the sensed flow from the beginning of the inspiration to the beginning of the exhalation, and means for declaring disconnection of the patient tubing system has occurred if the exhalation volume is less than the integral of the net flow from the beginning of inspiration to the beginning of exhalation with respect to time, multiplied by a proportional factor and a disconnection sensitivity factor, for three consecutive breaths.

REMARKS

In light of the foregoing amendments, favorable consideration of the application is respectfully requested.

Respectfully submitted,

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By   
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DGP/rvw

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